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| APPLICATION NO.   | FILING DATE             | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------------------|----------------------|---------------------|------------------|
| 09/981,525  | 10/16/2001              | Fred Burbank         | 9619-1031           | 8046             |
| EDWARD J L  | 7590 04/17/2007<br>VNCH | EXAMINER             |                     |                  |
| DUANE MOR   | RIS LLP                 | FOREMAN, JONATHAN M  |                     |                  |
| ONE MARKET<br>SPEAR TOWER SUITE 2000<br>SAN FRANCISCO, CA 94105 |                         |                      | ART UNIT            | PAPER NUMBER     |
|   |                         |                      | 3736                |                  |
|   | <del></del>             |                      |                     |                  |
| SHORTENED STATUTOR  | Y PERIOD OF RESPONSE    | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS  |                         | 04/17/2007           | PAPER               |                  |

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|   |  | *  | <u> </u>  |  |  |  |
|---|--|--|---|--|--|--|
| P   |  | Application No.  | Applicant(s)  |  |  |  |
|   |  | 09/981,525   | BURBANK ET AL.  |  |  |  |
| Office Action   | n Summary  | Examiner   | Art Unit  |  |  |  |
|   |  | Jonathan ML Foreman  | 3736  |  |  |  |
| The MAILING DAT<br>Period for Reply   | E of this communication app  | ears on the cover sheet with the c   | correspondence address  |  |  |  |
|   | TORY PERIOD FOR REPLY  | Y IS SET TO EXPIRE 3 MONTH   | (S) OR THIRTY (30) DAYS   |  |  |  |
| WHICHEVER IS LONGE  - Extensions of time may be availa after SIX (6) MONTHS from the - If NO period for reply is specified - Failure to reply within the set or | R, FROM THE MAILING DA<br>sble under the provisions of 37 CFR 1.13<br>mailing date of this communication.<br>I above, the maximum statutory period wextended period for reply will, by statute,<br>later than three months after the mailing | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE , date of this communication, even if timely filed | N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133). |  |  |  |
| Status  |  |  |   |  |  |  |
| 1) Responsive to com  | nmunication(s) filed on <u>03 Ja</u>   | anuary 2007.   |   |  |  |  |
| 2a) This action is FINA   |  |  |   |  |  |  |
| •   |  |  |   |  |  |  |
| closed in accordan  | ce with the practice under E   | x parte Quayle, 1935 C.D. 11, 4  | 53 O.G. 213.  |  |  |  |
| Disposition of Claims   |  |  | • . •   |  |  |  |
| 4) Claim(s) 35-47 is/a  | are pending in the application   | n.   |   |  |  |  |
| ,   | aim(s) is/are withdray   |  | *   |  |  |  |
| 5) Claim(s) is/a  | are allowed.   |  |   |  |  |  |
| 6) Claim(s) 35-47 is/a  | are rejected.  |  |   |  |  |  |
| 7) Claim(s) is/s  | are objected to.   |  |   |  |  |  |
| 8) Claim(s) are   | e subject to restriction and/o   | r election requirement.  | · · · · · · · · · · · · · · · · · · ·                                       |  |  |  |
| Application Papers  |  | 4  | ,   |  |  |  |
| 9)☐ The specification is  | objected to by the Examine   | er.  |   |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |  |  |   |  |  |  |
|   |  | drawing(s) be held in abeyance. Se   |   |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |  |  |   |  |  |  |
| 11) The oath or declara   | ation is objected to by the Ex   | caminer. Note the attached Office  | e Action or form PTO-152.   |  |  |  |
| Priority under 35 U.S.C. § 1  | 119  |  |   |  |  |  |
|   |  | priority under 35 U.S.C. § 119(a   | )-(d) or (f).   |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents have been received.   |  |  |   |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |  |  |   |  |  |  |
|   |  | rity documents have been receiv  | •   |  |  |  |
| •   | rom the International Bureau   |  |   |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |  |  |   |  |  |  |
|   |  | 1  |   |  |  |  |
|   |  |  |   |  |  |  |
| Attachment(s)   |  |  | •   |  |  |  |
| 1) Notice of References Cited (I  | PTO-892)   | 4) Interview Summan  | (PTO-413)   |  |  |  |
| 2) Notice of Draftsperson's Pate  | ent Drawing Review (PTO-948)   | Paper No(s)/Mail D   | Pate  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 7/13/06;8/28/06.  5) Notice of Informal Patent Application 6) Other:                  |  |  |   |  |  |  |

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#### **DETAILED ACTION**

#### Information Disclosure Statement

The information disclosure statements filed 7/13/06 and 8/28/06 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. They have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

### Terminal Disclaimer

1. The terminal disclaimer filed on 1/3/07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,712,775 and U.S. Patent No. 6,454,727 has been reviewed and is NOT accepted.

The patent being disclaimed has been improperly identified since the number used to identify the patent being disclaimed is incorrect. The correct number is 6,454,727.

#### Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 3. Claims 35 37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,712,775. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 35 37 of the present application are merely broader than claim 1 of U.S. Patent No. 6,712,775 to Burbank et al. Therefore, any art meeting the limitations of claim 1 of U.S. Patent No. 6,712,775 would necessarily meet the limitations found in claims 35 37 of the present application.
- 4. Claims 35 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 9 and 17 of U.S. Patent No. 6,454,727 to Burbank et al. in view of U.S. Patent No. 6,494,881 to Bales et al.

In regards to claims 35 – 43, Burbank et al. discloses a tissue acquisition device useful in retrieving tissue samples from a patient, comprising: an Inner cannula having a proximal end, a distal end, a longitudinal axis extending between the proximal and distal ends, a tubular sidewall, a cut out in the sidewall and a main lumen extending within at least a portion of the inner cannula; an outer cannula having a proximal end, a distal end, a longitudinal axis extending between the proximal and distal ends, a tubular sidewall, a cutout in the tubular sidewall of the outer cannula and a main lumen extending within at least a portion of the outer cannula; a passageway extending longitudinally a long

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the device from the proximal end toward the distal end; a cutting wire slidably and rotatably disposed in the passageway, having a proximal end and a distal end and having a cutting loop at a the distal end which extends out of the passageway and which is configured to rotate out of the inner cannula to a position exterior to the outer cannula, to move longitudinally in a direction generally parallel to the longitudinal axis exterior to the outer cannula and to rotate from a position exterior to the outer cannula into the inner cannula (Claim 1). Burbank et al. discloses an end plug mounted at the distal ends of the inner cannula and the outer cannula (Claim 5) which comprises a cutting wire extending distally from the end plug and separated from the end plug by a gap, the cutting wire including a connecting portion embedded in the end plug, extending proximally through the end plug, and exiting the end plug proximally, the cutting wire including a free end opposite the connecting portion which is embedded in the end plug (Claim 8), wherein the inner cannula further comprises a conductor extending through the inner cannula sidewall from the proximal end to the distal end, the conductor having a distal end in electrical contact with the end plug cutting wire (Claim 9) Burbank et al. discloses the outer cannula comprising an electrically conductive material on a portion of the exterior of the outer cannula, and the outer cannula being a return electrode for the cutting loop. However, Burbank et al. fails to disclose the cutting wire or distal cutting wire being formed of a material selected from the group consisting of stainless steel, tungsten, platinum, and nickel-titanium alloy and being connected to a source of radio-frequency electrical energy. Bales et al. discloses a cutting wire being formed of a material selected from the group consisting of stainless steel, tungsten, platinum, and nickel-titanium alloy (Col. 13, lines 26 - 30) and being connected to a source of radio-frequency electrical energy (Col. 5, lines 17 – 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the loop electrode as disclosed by Burbank et al. to include a material selected from the group consisting of

stainless steel, tungsten, platinum, and nickel-titanium alloy and being connected to a source of radio-frequency electrical energy as taught by Bales et al. in order to simultaneously cut and cauterize the tissue during a tissue acquisition procedure (See Abstract).

#### Claim Objections

5. Claim objected to because of the following informalities: Claim 44 recites "sidewall" as well as "side wall". Appropriate correction is required in order to be consistent.

### Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 7. Claims 44 47 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regard to claim 44, the limitation "the outer cannula" in line 14 lacks antecedent basis in the claim.

## Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 9. Claims 44 46 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,810,806 to Ritchart et al.

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In regard to claims 44 – 46, Ritchart et al. an elongated probe member (36) having a proximal end, a distal end, a longitudinal axis extending between the proximal and distal ends, a tubular sidewall, a cut out (38) in the sidewall and an inner lumen extending within at least a portion of the elongated probe member and in fluid communication with the cut out; an electrically conducting cutting wire that is slidably and rotatably disposed in the passageway, which has a distal end and a cutting loop (20) at the distal end that is configured to rotate (Figure 3) out of the cut out in the sidewall to a position exterior to the probe member, to move longitudinally in a direction generally parallel to the longitudinal axis (Col. 9, lines 32 – 36) exterior to the probe member and to rotate from a position exterior to the outer cannula into the probe member through the cut out in the sidewall. The cutting wire is electrically connected to a source of RF electrical energy (Col 7, lines 51 – 54). The cutting wire is formed in part of a material selected from the group consisting of stainless steel, tungsten, platinum, and nickel-titanium alloy.

### Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,810,806 to Ritchart et al. as applied to claim 44 above and further in view of US Patent No. 5,947,964 to Eggers et al.

In regards to claim 47, Ritchart et al. disclose a tissue acquisition instrument including an elongated shaft with a distal end having a cutting element adapted for entry into a patient's body, but

fail to disclose an electrosurgical cutting element. However, Eggers et al. teaches a needle adapted for entry into a patient's body having an electrosurgical cutting wire (29; Col. 6, line 49) located on the distal end an elongated shaft. It would have been obvious to on having ordinary skill in the art at the time the invention was made to modify the cutting element as disclosed by Ritchart et al. to be an electrosurgical cutting wire as taught by Eggers et al. in order to simultaneously cut and cauterize while inserting the instrument into the tissue.

### Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view 12. of the new ground(s) of rejection.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMLF